

REMARKS

In the Office Action, the Examiner raised an enablement rejection, a written description rejection, two anticipation rejections, and two nonstatutory obviousness-type double patenting rejections. Each of the rejections is addressed separately below. A 37 C.F.R. § 1.132 Declaration is submitted herewith to support the application. In view of the amendments noted above, the declaration submitted herewith, and the remarks below, reconsideration of the merits of this patent application is respectfully requested.

No extension of time is believed to be necessary and no fee is believed to be due in connection with this response. However, if any extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

Enablement rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-3, 5-10, 13-15, 17-22, 25, and 26 under 35 U.S.C. § 112, first paragraph for failing to comply with the enablement requirement. In particular, the Examiner alleged that the specification, while being enabling for administering anti-PLA₂ antibodies, does not reasonably provide enablement for administering the genus of all agents that reduce the bioavailability of a prostaglandin or leukotriene lipid precursor such that body weight uniformity or carcass yield is increased.

Without agreeing with the rejection, claims 1 and 13 are amended to recite an anti-PLA₂ antibody and claims 2-4 and 14-16 are canceled to facilitate prosecution. Applicant reserves the right to pursue the canceled subject matter in a continuation application.

The rejection is believed to have been overcome by the amendments.

Written description rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-3, 5-10, 13-15, 17-22, 25, and 26 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. In particular, the Examiner alleged that the applicant disclosed anti-PLA₂ antibodies and such a disclosure does

not support the broad genus of any agent that is capable of reducing the bioavailability of a prostaglandin or leukotriene lipid precursor.

Without agreeing with the rejection, claims 1 and 13 are amended to recite an anti-PLA₂ antibody and claims 2-4 and 14-16 are canceled to facilitate prosecution. Applicant reserves the right to pursue the canceled subject matter in a continuation application.

The rejection is believed to have been overcome by the amendments.

Anticipation rejections under 35 U.S.C. § 102 (b) over U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485

The Examiner rejected claims 1-10, 12-22, and 24-26 as being anticipated by U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485. In particular, the Examiner alleged that improvement in body weight uniformity and increased carcass yield would be inherently achieved by practicing the methods taught by U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485. The Examiner cited *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999), *In re Best*, 562 F.2d 1252, 1254 (CCPA 1977) and other court cases for support. Applicants respectfully traverse the rejections.

As an initial matter, applicant notes that inherency may not be established by probabilities or possibilities and the mere fact that a certain thing may result from a given set of circumstances is not sufficient (*Continental Can Co. USA, Inc. v. Monsanto Co.*, 984 F.2d 1264, 1268-69 (Fed. Cir. 1991)). To support an anticipation rejection based on inherency, an examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teaching of the prior art (*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Inherency must flow as a necessary conclusion from the prior art, not simply a possible one (*In re Oelrich*, 666 F.2d 578, 581 (CCPA, 1981)). Here in this case, the Examiner has not provided factual and technical grounds establishing that the inherent feature necessarily flow from the teaching of the prior art and applicant herein provides evidence that the allegedly inherent characteristic (improvement in body weight uniformity or increased carcass yield) does not necessarily flow from the teachings of the applied art.

Claim 1 as amended recites administering an anti-PLA₂ antibody in an amount sufficient to improve body weight uniformity and claim 13 as amended recites administering an anti-PLA₂

antibody in an amount sufficient to increase carcass yield. Both U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485 disclose administering 0.0-0.5 g dietary dried egg yolk (containing anti-PLA₂ antibodies) per Kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE" of both said U.S. patents. Therefore, the desirable effects of the two prior art U.S. patents of enhancing growth/feed behavior (U.S. Patent No. 6,213, 930) and reducing gastrointestinal inflammation (U.S. Patent No. 6,383,485) are achieved at a dosage of $\leq 0.05\%$ by weight.

With respect to claim 1 of the present application relating to improving body weight uniformity, Example 1 of the application shows the results from feeding anti-PLA₂ antibody egg yolk powder at a dosage of 0.3 to 2.4 g per Kg of feed (0.03-0.24% by weight). While a statistically significant difference in the coefficients of variation of mean body weight was observed when all anti-PLA₂ antibody fed groups (0.03-0.24% by weight = 0.3-2.4 g/Kg feed) were analyzed together (the P value was set at < 0.1), there was no statistically significant difference in the coefficients of variation of mean body weight when the analysis only included groups fed a dosage of 0.05% or lower ($P = 0.379$), which corresponds to the dosage in the two prior art U.S. patents cited by the Examiner. This is explained in the 37 C.F.R. § 1.132 Declaration attached. In other words, practicing the methods disclosed in U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485 would not lead to an improvement in body weight uniformity, much less that this specific result would necessarily flow from practicing the prior art methods.

Similarly, with respect to claim 13 of the present application relating to increasing carcass yield, the dosages used in the present application to achieve this effect is 0.1%, 0.2%, or 0.4% (see Example 2 of the application), which is at least twice as much as the highest dosage used in U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485. Given this dosage difference, the Examiner has not provided factual grounds as required by law to establish that practicing the methods of the two prior art U.S. patents at a dosage significantly lower than those used in the present application would necessarily lead to higher carcass yield. The evidence provided above in connection with improving body weight uniformity indicates that higher carcass yield may not be achieved. Applicant notes again that inherency may not be established by probabilities or possibilities and the mere fact that a certain thing may result from a given set of circumstances is

not sufficient (*Continental Can Co. USA, Inc. v. Monsanto Co.*, 984 F.2d 1264, 1268-69 (Fed. Cir. 1991)).

For the above reasons, withdrawal of the anticipation rejections is respectfully requested.

With respect to *Atlas Powder Co. v. Ireco Inc.* cited by the Examiner for the proposition that "the discovery of a previous unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer," applicant notes that the quote clearly concerns claiming old compositions with a new property. The word "method" in parentheses was not in the quote. The Examiner added it to the quote. This is not appropriate because it broadens the holding of the case not intended by the court. Process claims are treated differently from composition claims. 35 U.S.C. § 101 provides "[w]hoever invents or discovers any new and useful process ... may obtain a patent therefor..." 35 U.S.C. § 100(b) defines that the term "process" in 35 U.S.C. § 101 can mean a new use of a known process: "[t]he term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." Applicant acknowledges the *In re Best* case cited by the Examiner. As the Examiner pointed out, the court in *In re Best* said that the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. Applicant respectfully notes that by using the words "not necessarily," the court indicates that the claiming of a new use may sometimes be patentable, which is consistent with 35 U.S.C. §§ 100(b) and 101. It is noted that the claims at issue are not directed at old compositions based on new properties such as the case in *Atlas Powder Co. v. Ireco Inc.* but rather methods of using a known agent (anti-PLA₂ antibody) based on the newly discovered activity of the agent.

Lastly, it is noted that new added claims 27 and 28 contain an observation step that is supported by the examples of the application. Neither U.S. Patent No. 6,213,930 nor U.S. Patent No. 6,383,485 explicitly or inherently disclosed the observation step and, therefore, new claims 27 and 28 are not anticipated by either of the U.S. patents.

Nonstatutory obviousness-type double patenting rejections

The Examiner rejected claims 1-10, 12-22, and 24-26 on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-11 of U.S. Patent No. 6,213, 930 and claims 1-11 of U.S. Patent No. 6,383,485. In particular, the Examiner alleged that although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant invention. Applicant respectfully traverses the rejection.

As already discussed in connection with the anticipation rejections above, the claims at issue as amended are not anticipated by U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485. Applicant has also addressed the two court cases (*Atlas Powder Co. v. Ireco Inc.* and *In re Best*) cited by the Examiner in connection with the anticipation rejections. Just because an agent can enhance growth/feed behavior (U.S. Patent No. 6,213, 930) and reduce gastrointestinal inflammation (U.S. Patent No. 6,383,485) does not make it obvious that the agent can improve body weight uniformity in a group of animals. Similarly, it is not obvious that the agent can increase carcass yield because the improvement in growth/feed behavior and the reduction in gastrointestinal inflammation may very well lead to equal growth improvement in all body parts or the body parts that do not end up in the animal carcass, which would result in either no carcass yield improvement as defined in paragraph [00019] of the application or even a decrease in carcass yield.

For the above reasons, withdrawal of the non-statutory obviousness-type double patenting rejections is respectfully requested.

Summary

Having addressed each issue raised by the Examiner, claims 1, 5-10, 12, 13, 17-22, and 24-28 as amended are believed to be in condition for allowance and a Notice of Allowance is respectfully requested. Should any issues remain outstanding, the Examiner is invited to contact

the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Respectfully submitted,



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